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Cost, coverage, and the underuse of medications among people with CF

By Semret Seyoum, Marsha Regenstein, and Lea Nolan
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Introduction

Use of recommended therapies is essential to improving health outcomes and maintaining quality of life for people with cystic fibrosis (CF). People with CF face a constellation of challenges that can affect their ability to follow their care team's recommendations related to prescription and non-prescription medication orders. Factors outside the patient's control, such as medication costs, complicated insurance approval processes, and the responsibilities associated with managing everyday lives, can impact their access to medications. The high out-of-pocket cost of medications can become a major barrier to the use of recommended therapies for people with CF as well as for many other chronic conditions. One study found nearly one of every six *insured* Americans did not fill a prescription or skipped at least one dose in the previous year due to the cost.¹ This is even more common among the uninsured; one in three *uninsured* people in the U.S. did not fill a prescription or skipped a dose because of the cost.¹ While the vast majority of people with CF are insured, that does not mean that they are shielded from burdensome out-of-pocket costs. Even with insurance coverage, people with CF are often responsible for cost sharing and other out-of-pocket expenses that can quickly add up.

In this brief, we attempt to better understand the factors associated with underuse of prescription medications due to cost for people with CF. We describe the characteristics of people who experience this challenge, including insurance type and gaps in coverage, costs to the patient, the financial hardships they face, and the ways that these hardships affect use of CF care center services.

We find that there is a clear association between financial challenges or coverage inadequacies and underuse of prescription medications among people with CF.

Methods

Under contract from the Cystic Fibrosis Foundation, researchers from the Milken Institute School of Public Health at George Washington University developed an online survey, The 2019 Cystic Fibrosis Health Insurance Survey, to understand unmet medical need, coverage, access to care, and financial hardship among people with cystic fibrosis in the U.S.² As part of the survey, participants were asked a series of questions to determine any unmet prescription drug need due to cost. Unmet prescription drug need – which we refer to throughout this report as “unmet Rx need” – was determined to be present if the respondents indicated they had skipped medications doses, taken less medicine than prescribed, or delayed filling a prescription in the past year due to the cost.

Survey participants were recruited with assistance from the Cystic Fibrosis Foundation. The Foundation shared the survey across the U.S. using social media and listservs, while also encouraging providers at CF care centers to share the survey with their patients. All respondents represent a unique person with CF (even if the survey was filled out by a parent on behalf of their child or a caregiver on behalf of someone with CF). The cross-sectional survey was fielded from July to December 2019. The final sample includes 1,846 participants. The sample was weighted to reflect the parameters of the CF Foundation’s 2019 Patient Registry Annual Data Report; it is representative of the population of individuals in the U.S. who have CF and who seek care at one of the 133 accredited care centers.³ Survey weights were applied to adjust for non-responses by age group and insurance type.⁴

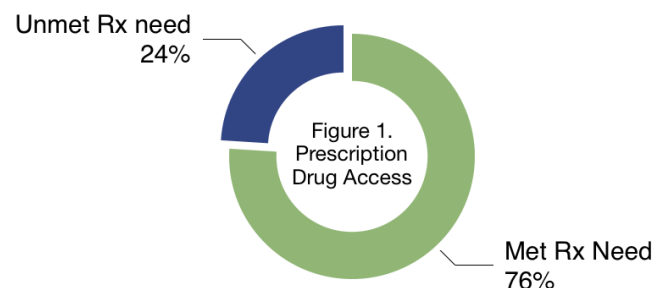
Descriptive and bivariate quantitative analyses were conducted to explore the subpopulation with unmet Rx need and make comparisons to those whose Rx needs are met. Multiple logistic regressions were also utilized to examine the association between financial and coverage-related risk factors, underutilization of care center services, and unmet Rx need.

This survey was conducted before the COVID-19 outbreak and overlapped with the October 2019 approval of Trikafta®, a highly effective treatment that could eventually be available to 90% of people with CF. Any additional challenges with COVID-19 regarding access to care and financial hardship will not be captured in this issue brief.

Demographics

Overall, one out of every four people with CF (24%) indicated that they had an unmet Rx need in 2019 (Figure 1).

Unmet Rx need varies depending on some characteristics of people with CF. Gender, race, ethnicity, geographic area, and employment, however, do not have a significant association with unmet Rx need. Our data indicate a potentially large disparity across race on unmet Rx need. In our sample, 37% of Black or African American people with CF indicate unmet Rx



compared to 24% of white people with CF. Given that only 3% of the total sample is Black, however, these differences by race do not hold statistical significance.

Unmet Rx need varies greatly by age. As shown in Figure 2, one third of adults with CF have unmet Rx need due to cost. Children (0-17 years old) are less likely to report skipped or delayed medications compared to adults ages 18 and above (13% versus 34% respectively). The odds of unmet Rx need are three times higher for adults than children ($p < .001$), holding insurance and household income constant.

Figure 2. Percentage of People with CF with Unmet Rx Need by Age

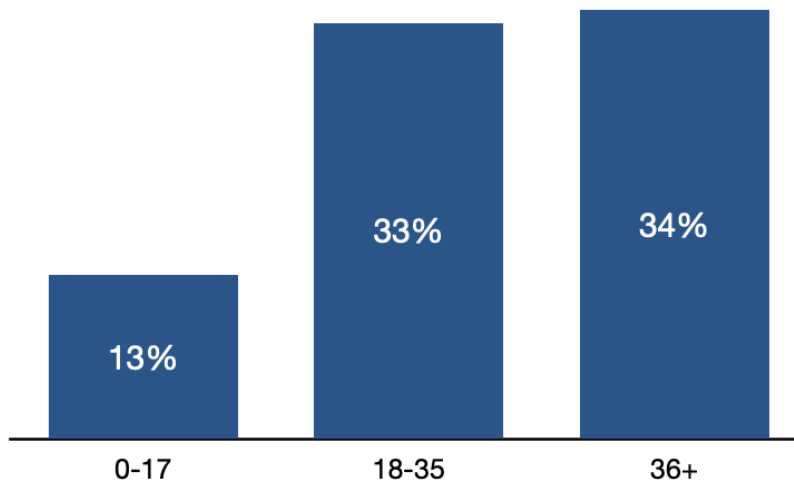


Table 1 showcases the odds of unmet Rx need by differences in age group, while controlling for differences in household income and insurance.

Table 1. Adjusted Odds Ratio of Unmet Rx Need by Age of Person with CF

Age	Adjusted Odds Ratio
0-17	(Reference)
18-35	3.268***
36+	3.292***

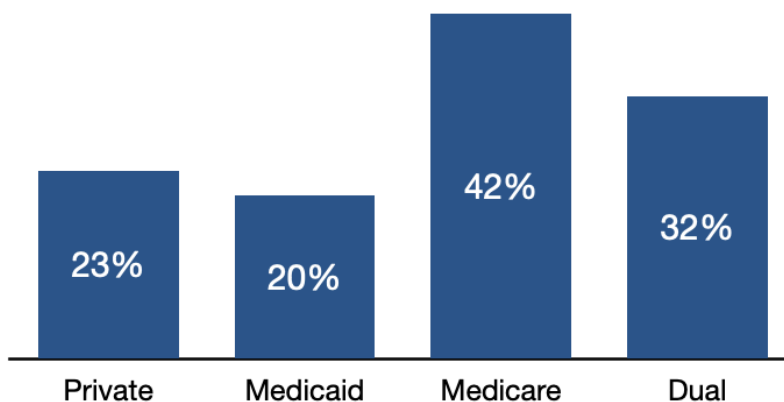
Note: Odds ratios are adjusted to hold household income and insurance constant. *** Denotes there is a statistically significant association between the age group and unmet prescription drug need at a p -value $< .001$.

The odds of unmet Rx need are three times higher for adults than children ($p < .001$), holding insurance and household income constant. This may be due to the reduction of parental support in managing care or increased risk of financial instability among adults. Children may be granted more protections through coverage, financial assistance programs, or the financial stability of parents or guardians.

Insurance

In Figure 3, we look more closely at unmet Rx need due to cost within different coverage groups. About one in five people with CF with Medicaid or private insurance have delayed or skipped medications due to cost. A larger portion of Medicare beneficiaries and people with CF dually insured by Medicaid and Medicare have unmet Rx need (42% and 32% respectively).

Figure 3. Percentage of People with CF with Unmet Rx Need by Coverage Type



In Table 2, we examine the odds of unmet Rx need due to cost if a person with CF has some public insurance compared to private insurance, while controlling for differences in age and household income.

Table 2. Adjusted Odds Ratio of Unmet Rx Need by Insurance Type of Person with CF

Insurance Type	Adjusted Odds Ratio	P-value
Private	(Reference)	(Reference)
Medicaid, CHIP, State Program	0.854	0.337
Medicare	1.430	0.074
Dual	0.715	0.290

Note: Odds ratios are adjusted to hold age and household income constant. P-values suggest that the relationship between insurance types and unmet Rx need is not statistically significant at a $p < .05$.

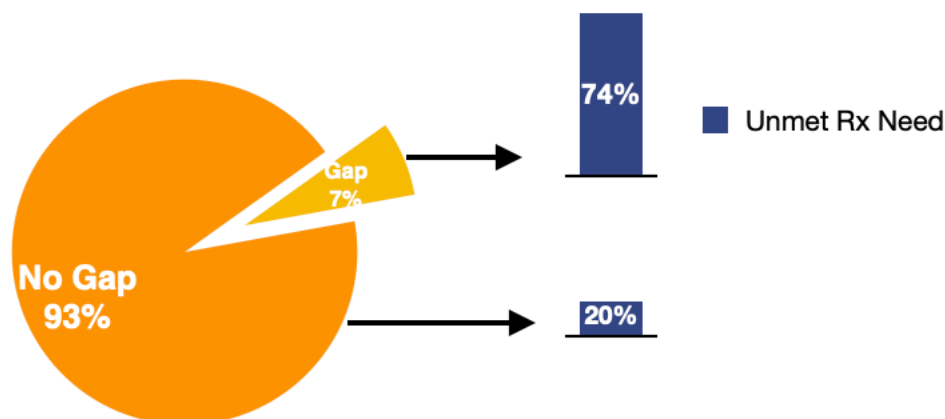
Medicare beneficiaries stand out as having an increased risk of unmet Rx need. This is in part because the majority of people with CF who qualify are sicker; and in part because of the way that Medicare functions, where beneficiaries face cost-sharing requirements without a catastrophic limit that is common to private insurance plans. The cost of coinsurance and aggregate out-of-pocket expenses may impose a higher financial burden on Medicare beneficiaries and increase the risk of unmet Rx need.

The odds of unmet Rx need are 43% higher for Medicare beneficiaries than individuals who are privately insured, controlling for age and household income ($p=.07$). Associations between insurance type and unmet Rx need lose statistical significance when we adjust for differences by age. Table 1 shows that unmet Rx need is more attributable to age than to differences in coverage. The odds of unmet Rx need are not significantly different among Medicaid beneficiaries (including those dually covered by Medicare) and the privately insured.

Gaps in Coverage

Fewer than one percent of people with CF indicated that they were uninsured at the time they completed the survey. Given the importance of insurance coverage for people with CF, we asked survey respondents who had insurance coverage at the time of the survey if there was a time in the past year when they had a gap in coverage – in effect whether they were uninsured for any part of the previous 12 months. The majority of respondents (93%) had coverage for the entire 12-month period. Yet our study indicates that people with any gap in coverage are particularly vulnerable to going without their necessary medications.

Figure 4. Percentage of People with CF with Unmet Rx Need who had a Gap in Coverage



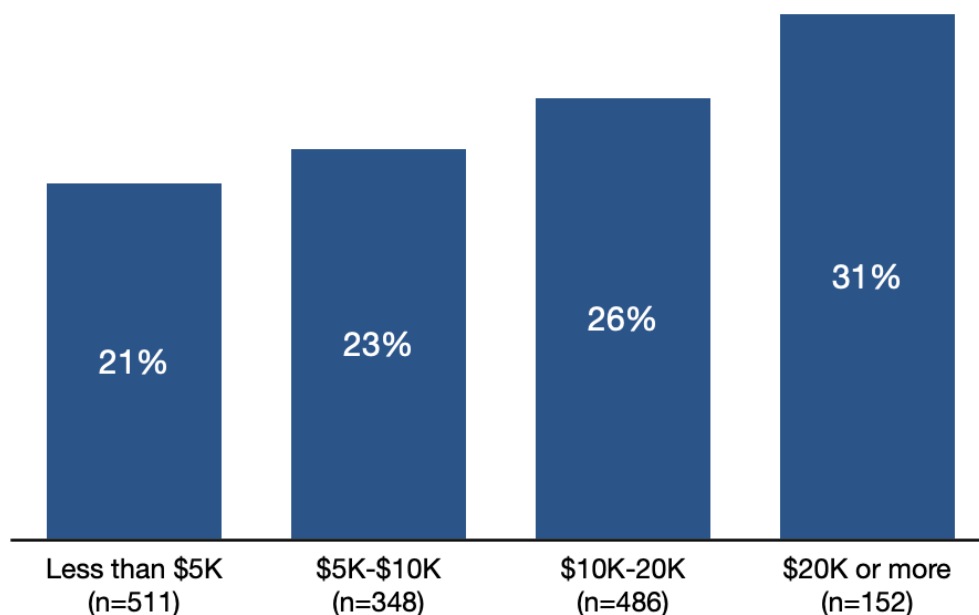
As shown in Figure 4, 74% of people with CF who had a gap in coverage also reported some unmet Rx need. This explains why it's so vital for people with CF to maintain coverage at all times. A minor gap in coverage can have an immediate effect on someone's ability to get care. This compares to 20% of people who had coverage for the full prior 12-month period who indicate that they had some difficulty accessing Rx due to cost.

Costs to the Patient

The complex array of CF-related medications, services, and equipment required for CF-management can be extremely costly. Though most people with CF have some form of insurance to help cover these costs, patients still face the burden of cost sharing and other out-of-pocket expenses. Even when individual co-payments or cost-sharing are relatively modest for any single drug or service, the multitude of out-of-pocket expenses can quickly

add up. So too can the costs of monthly insurance premiums and deductibles. To estimate the total cost that the patient incurs managing their health care, participants were asked to report how much they spend on household's premiums, deductibles, and other out-of-pocket expenses.⁵ These costs to the patient could include the premiums for a family plan or other household expenses that are not directly attributable to the person with CF. The median out-of-pocket expenses that people with CF pay is \$8,244. Figure 5 shows unmet Rx drug need by total annual health care costs.

Figure 5. Percentage of People with CF with Unmet Rx Need by Total Out-of-Pocket Expenses Accrued



As the out-of-pocket expenses accrued increases within a household, the likelihood of unmet Rx need also increases. Thirty-one percent (31%) of people with CF who spend \$20K or more annually out-of-pocket report that they have some unmet Rx need. However, there is a significant risk of unmet need regardless of total cost to the patient. For instance, 22% of the group of people who spend \$10K or less annually on their care report some unmet Rx need.

While out-of-pocket expenses are associated with increases in the likelihood of unmet Rx need, these expenses do not appear to be as strong a predictor of unmet Rx need as Medicare coverage, household income, or age. Unmet need is fairly distributed by out-of-pocket expenses, with people who are paying more being somewhat more likely to experience unmet Rx need. Much of this may be associated with age and income. Children and young adults with CF tend to pay less out-of-pocket expenses than older adults with CF; expenses accrued are dependent on the coverage the person with CF has and often is associated with income level.

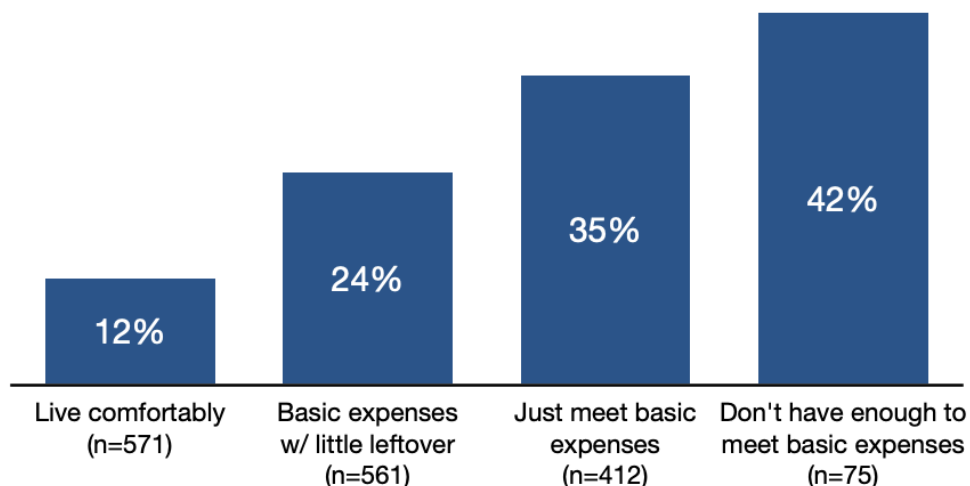
Even people who pay relatively little out of pocket may still face some unmet Rx need. Nonfinancial factors such as transportation, health literacy, cultural differences, and provider availability can play a role in reducing patients' access to needed health care services.⁶ For example, the cost of transportation to obtain prescriptions may be high enough that it leads to delaying or skipping medications. For people with CF, over-the-counter non-prescription medications may not be covered by state Medicaid programs therefore putting additional financial pressure on the patient to purchase these products to fully meet Rx needs. Participants were also asked if they have some form of financial assistance, such as grants from care centers or patient assistance programs from drug companies. *Three-quarters of people with CF (74%) reported they have at least one form of financial assistance, although for some, this does not adequately relieve the financial need; 28% of people with CF within that group have some unmet Rx need even with these extra supports.*

Financial Burden

Household Finances

In order to estimate financial burden within a person with CF's household, we asked survey respondents to indicate which scenario best describes their household's financial situation: whether they live comfortably, meet basic expenses with a little leftover for extras, just meet basic expenses, or don't have enough to meet basic expenses (Figure 6).

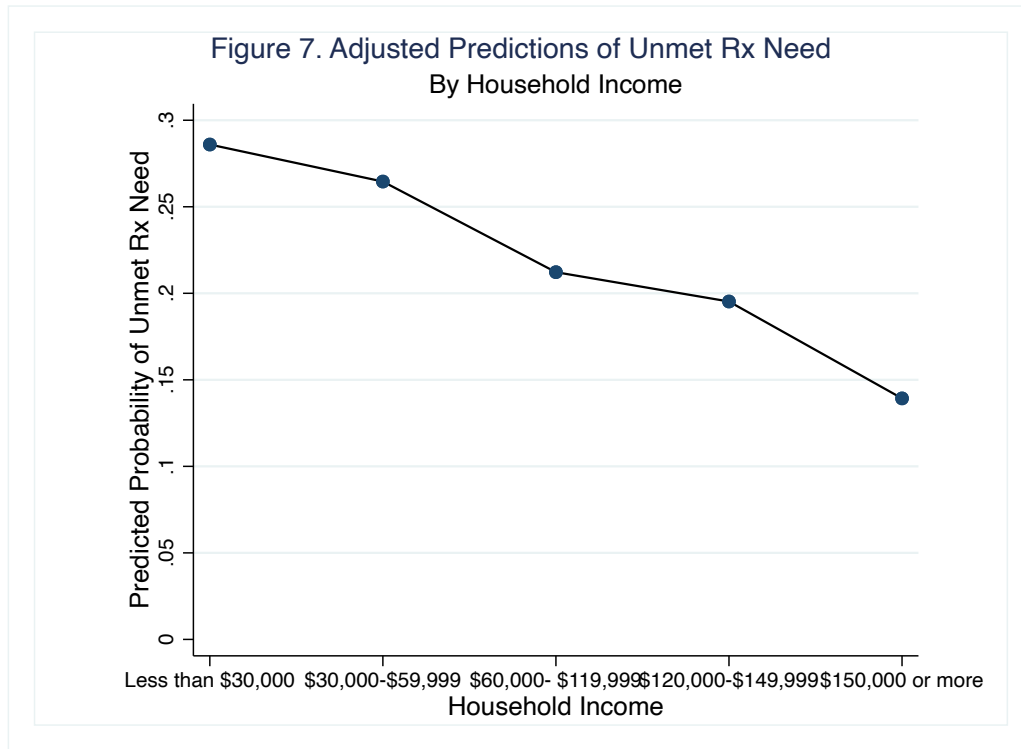
Figure 6. Percentage of People with CF with Unmet Rx Need by Household Financial Situation



About one in ten people with CF (12%) who live comfortably have delayed or skipped prescriptions due to cost. *As a person with CF's household financial situation worsens, however, the likelihood of unmet Rx need increases. 42% of people with CF who don't*

have enough to meet basic expenses report that they delayed or skipped medications due to cost.

Figure 7 showcases the probability of unmet Rx need by household income, while adjusting for differences in age and insurance.



As household income increases, the probability of unmet Rx needs decreases. If you have a household income less than \$30,000, you have 29% chance of unmet Rx need ($p < 0.001$). The odds of unmet Rx need in these households is two and a half times higher than households with \$150,000 or more ($p < .001$). People with CF in households with \$150,000 or more in income have a 15% chance of unmet Rx need, and, therefore, are also not immune to the financial burden of managing CF therapies. Clearly, while income protects people with CF from unmet Rx needs, it does not completely eliminate the likelihood that these challenges exist.

Problems Paying for Medications and Supplements

In addition to the focus on unmet Rx need, we also looked at the affordability of specific medications. We worked with the CF Foundation to identify common prescription and over-the-counter medications and supplements. About one-third (32%) of people with CF had problems affording these common CF medications.

Figure 8. Percentage of People With CF Who Had a Problem Paying for Medications or Supplements

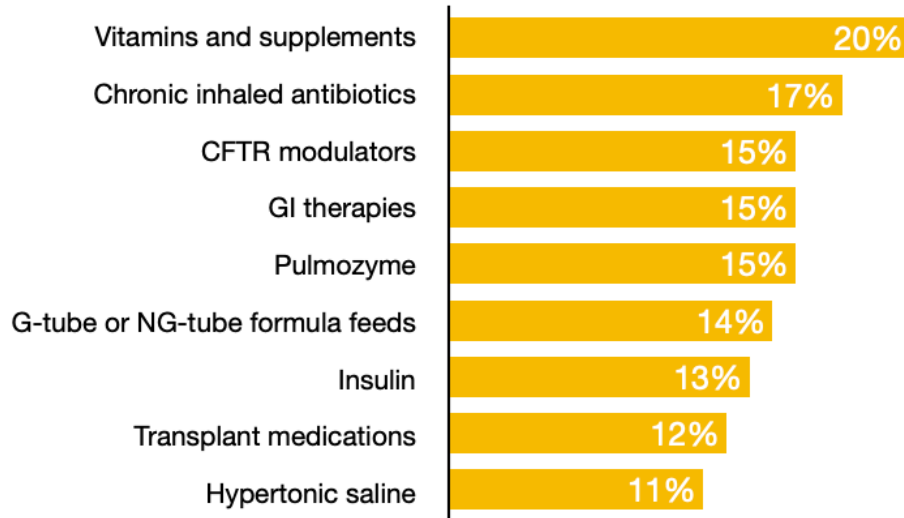


Figure 8 shows that between 11% and 20% of people with CF have a problem affording certain medications or supplements. For example, 17% of the sample had a problem paying for chronic inhaled antibiotics; and 15% had a problem paying for CFTR modulators. Our data indicate that people with CF who had problems paying for medications may be at risk for delayed or skipped prescription medications. There are many social factors at play that may contribute to this. Vitamins and supplements were most commonly reported as difficult to afford (20%). Though it may seem like people who have problems paying for supplements are more likely to have an unmet Rx need than those with problems affording other medications, the trend is actually common across the board of medications and supplements.

Figure 9. Percentage of Unmet Rx Need Among Those Who Had Any Problem Affording Medications or Supplements

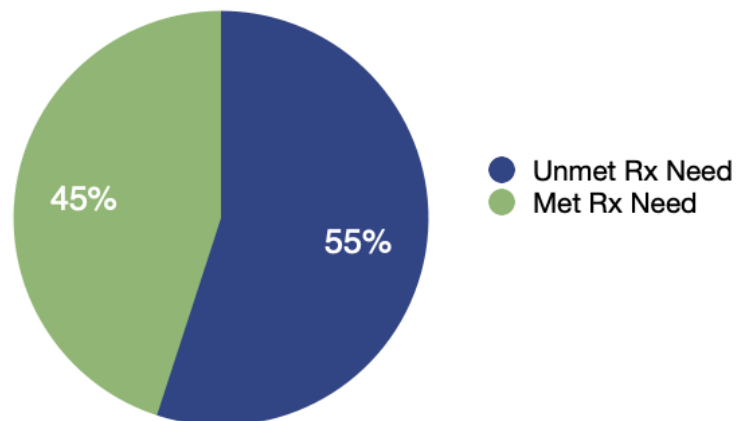


Figure 9 highlights the unmet Rx need among people who already have problems paying for medications. More than half of people with CF (55%) who had any difficulty affording medications or supplements reported some unmet Rx need. Three-fifths (59%) of people who had a problem paying for chronic inhaled antibiotics reported unmet Rx need. Likewise, almost half (47%) of people who had difficulty affording vitamins and supplements had unmet Rx need. Unmet Rx need varies from about 45% of people who had problems paying for G-tube or NG-tube formula feeds, to 64% of those having trouble paying for insulin.

Unsurprisingly, difficulty paying for medications and supplements is a key factor for unmet Rx need. If people with CF are having problems affording their medications or supplements this could be a warning sign that they are not taking medications.

In Table 4, we explore the odds of unmet Rx drug need if a person with CF has a problem paying for any medications compared to a person with CF who has no problem affording medications, adjusting for insurance and household income.

Table 4. Adjusted Odds Ratio of Unmet Rx Need by Problems Paying for Medications or Supplements

Financial Burden	Adjusted Odds Ratio
No problem paying for medications	(Reference)
Any problem paying for medications	6.343***
<i>Note:</i> Odds ratios are adjusted to hold insurance and household income constant. *** Denotes that statistically significant difference between the two groups at a p-value <.001.	

The odds of unmet Rx need are six times higher among people who have a problem paying for at least one medication or supplement than those that do not have any problem paying for medications or supplements, holding insurance and household income constant.

Household finances and medication affordability have a clear impact on unmet Rx need due to cost. When a person with CF is struggling to meet their basic expenses or has difficulty trying to pay for any medication, they are more likely to compensate by taking less medicine or delaying filling a prescription.

CF Care Center Visits

The CF care center is a core component of care for people with CF. The CF Foundation has established a standard of high-quality, specialized CF care that is centralized within accredited care centers. The Foundation’s model for care is associated with more efficient health care delivery and improvements in health outcomes (such as the median predicted survival age) for patients.^{7,8} The model recommends people with CF make four routine visits to their care center annually. People with CF are also likely to go to CF care centers when sick unless they require some emergency care. As a result, we sought to examine barriers to accessing CF care center care for both routine and sick visits, as well as the

impact of these barriers on unmet Rx needs. As shown in Table 5, 10% of the sample reported that they skipped a routine visit to their care center. Among those who skipped a routine care center visit, 53% reported some problem paying for routine visits. In this same group, 68% reported an unmet Rx need due to cost.

Table 5. Underutilization of CF Care Center Services and Unmet Rx Need

	Percentage of People with CF	Percentage Who Had a Problem Paying for Care Center Visit, Among Those Who Delayed or Skipped Care Center Visit	Percentage of Who Had Any Unmet Rx Need, Among Those Who Delayed or Skipped Care Center Visit
Skipped routine CF care center visit(s)	10%	53%	68%
Delayed CF care center visit when didn't feel well	10%	37%	68%

People with CF who delayed or skipped a care center visit due to cost are more likely to also have a problem affording common medications and to delay or skip prescription medications due to cost. This has potentially significant implications for assuring that people with CF receive the appropriate specialized care to maintain health.

In Table 6, we explore the odds ratios of unmet Rx need if a person with CF delayed or skipped care center visits compared to if a person with CF did not delay or skip care center visits, adjusting for insurance and household income.

Table 6. Adjusted Odds Ratio of Unmet Rx Need by Delays in Care Center Visits

Care Center Access	Adjusted Odds Ratio
Routine Visit	
Did not skip	(Reference)
Skipped	7.128***
Sick Visit	
Did not delay	(Reference)
Delayed	6.664***

Note: Odds ratios are adjusted to hold insurance and household income constant. *** Denotes that statistically significant difference between the two groups at a p-value <.001.

The odds of unmet Rx need are seven times higher among people with CF that skipped routine visits than among those who do not skip routine visits, holding insurance and household income constant.

We also examined delayed care center visits when the person did not feel well. As shown in Table 5, 10% of the sample reported delaying a sick visit to their care center. More than

one-third (37%) of this group additionally had a problem paying for sick care center visits. When we account for unmet Rx need, we find that 68% of people with CF who delayed sick visits to their care center also delayed or skipped prescription medications due to cost. As shown in Table 6, *the odds of delayed prescription medications are 6.7 times higher among people with CF that delay sick visits to their care center than among those who do not delay sick visits, holding insurance and household income constant.*

Unmet Rx need is undoubtedly tied to unmet medical need at CF care centers. People with CF are more likely to delay or skip taking their medications if they are already skipping or delaying their care center visits and having trouble affording care center visits.

Conclusion

The costs of CF medications that fall onto the person with CF affect their ability to get care. Family income and the cost of insurance play a critical role in preventing or exposing people with CF to unmet Rx need. Our data indicate that aging out of childhood, lower household income, gaps in coverage, and higher out-of-pocket costs to the patient greatly increase the likelihood of unmet Rx need. Medicare beneficiaries seem to be vulnerable to factors, such as higher out-of-pocket expenses, that prohibit them from maintaining appropriate doses of medications. People with CF who already experience some financial hardship, whether it's affording their basic living expenses or the various medications and ongoing care that they require, are also extremely vulnerable to unmet Rx need due to cost. Interventions could be made to monitor use of recommended medications and offer appropriate financial support when a person with CF experiences signs of financial hardship or coverage inadequacies.

Acknowledgements

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Endnotes

¹ Sarnak DO, Squires D, Kuzmak G, Bishop S. Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? The Commonwealth Fund.

<https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> Published 2017

² The survey used previously validated questions from national surveys related to unmet medical need, coverage, access to care, and financial hardship. Some questions were modified to fit the CF population's experience, and developed new CF-specific questions about services, treatments, and supplies with input from CF Foundation staff and advisors. The survey also included questions on socio-demographic characteristics, general health, CF-related illness and challenges, insurance benefits and coverage, access to care, and costs of CF care.

³ Cystic Fibrosis Foundation Patient Registry 2019 Annual Data Report Bethesda, Maryland ©2020 Cystic Fibrosis Foundation.

⁴ People with CF were categorized into three age groups- children 0-17 years old, young adults 18-35 years old, and older adults 36 years and above. For insurance, we identified six unique categories- private, Medicaid, Medicare, Duals, other, and uninsured. To account for people with multiple insurance types we identified respondents as belonging to one insurance category, using the following decision criteria:

- Medicaid: Respondents whose coverage is Medicaid, CHIP, or a state program. The Medicaid category includes respondents with any of these programs or respondents with other sources of coverage in addition to Medicaid, CHIP or a state program, except for respondents with Medicare, who are otherwise categorized (see below).
- Medicare: Respondents whose coverage is Medicare. The Medicare category includes respondents with Medicare alone or with any additional sources of coverage, except for respondents with Medicaid.
- Duals: Respondents whose coverage includes Medicare and Medicaid. The Duals category includes respondents with Medicare and Medicaid only, or respondents with Medicare, Medicaid and additional sources of coverage.
- Private: Respondents whose coverage is private. The private category includes participants with any other additional sources of coverage, except for Medicaid and/or Medicare.
- Other: Respondents whose coverage is not private, Medicaid, Medicare, or uninsured.
- Uninsured: Respondents who report they do not have insurance.

⁵ Participants were asked to select their premiums, deductibles, and other out-of-pocket expenses from given ranges. For each expense type, an upper bound was not specified. Instead, respondents were able to select some value "or more" as an option (e.g. "\$20,00 or more"). In order to estimate the total annual cost to the patient, the midpoint of each range was taken and summed to determine an estimated annual total cost to the patient.

⁶ Pharmacy Quality Alliance. Access to Care: Development of a Medication Access Framework for Quality Measurement. March 2019.

<https://www.pqaalliance.org/assets/Research/PQA-Access-to-Care-Report.pdf>

⁷ Mogayzel PJ Jr, Dunitz J, Marrow LC, Hazle LA. Improving chronic care delivery and outcomes: the impact of the cystic fibrosis Care Center Network. *BMJ Qual Saf.* 2014;23 Suppl 1:i3-i8. doi:10.1136/bmjqs-2013-002363

⁸ The Cystic Fibrosis Foundation. Care Centers. <https://www.cff.org/Care/Care-Centers/>